RECEIVED CENTRAL FAX CENTER

PAGE 07/30

SEP 2 8 2007

Attorney Docket No. 015225-005210US

(0051.00) Serial No. 09/731,316

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Examiner: Michael G. Mendoza

Schuler et al.

Art Unit: 3734

Serial No.: 09/731,316

Conf. No. 1043

Filed: December 6, 2000

Title: SYSTEMS AND METHODS FOR

TREATING PACKAGED POWDERS

SUPPLEMENTAL APPEAL BRIEF

Attention: Office of Petitions Mail Stop Petition Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In response to the Examiner's Final Rejection of October 6, 2005, the Applicant of the above-referenced patent application (hereinafter Appellant) hereby appeals to the Board of Patent Appeals and Interferences. Appellant requests the reversal of the Final Rejection.

RECEIVED CENTRAL FAX CENTER

PAGE 08/30

SEP 2 8 2007

PATENT Attorney Docket No. 015225-005210US (0051.00) Serial No. 09/731,316

(1) Real Party in Interest

The real party in interest of the present application is Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.), having a place of business at 150 Industrial Road; San Carlos, California 94707.

(2) Related Appeals and Interferences

Appellant, Appellant's legal representative, and assignee are aware of no appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal.

(3) Status of Claims

Claims 1-50 and 52-63 are presently pending in the case. Claim 51 has been cancelled. Claims 1-18, 21, 23-29, 35-39, 43-49, 61 and 62 have been finally rejected. Claim 52-60 have been allowed. Claims 19, 20, 22, 30-36, 40-42, 50, and 63 have been objected to as dependent claims containing allowable subject matter. The rejection of each of claims 1-18, 21, 23-29, 35-39, 43-49, 61 and 62 is hereby appealed.

(4) Status of Amendments

No amendments after Final Rejection have been filed. Accordingly, all amendments made during prosecution of the case have been entered.

(5) Summary of the Claimed Subject Matter

As discussed in the specification and as recited in claim 1, a method is provided for conditioning a packaged powder, such as an aerosolizable pharmaceutical powder. A pulse of energy is applied to a receptacle (10) having a chamber or cavity (18) which contains the powder. The pulse of energy serves to increase the efficiency at which the power may be extracted from the receptacle when the powder is aerosolized by flowing gas through the chamber, as discussed on page 11 line 14 through page 12 line 11.

The pulse of energy may be provided, for example, by striking the receptacle or by vibrating the receptacle. In one version, the pulse of energy involves quickly striking the receptacle with at least about 0.01 lbf-in of energy (see Figure 7 and 7A-7E, for

Attorney Docket No. 015225-005210US (0051.00)

Serial No. 09/731,316

example). In another version, the receptacle may be vibrated at a high frequency (see Figures 10 and 11, for example).

Independent claim 15 is directed to a powder conditioning system. The system comprises a receptacle (10) having an enclosed chamber (18) containing an amount of a powder and a mechanism (22) to provide at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber. The system also comprises an aerosolization mechanism (an example of which is discussed on page 13 lines 7-26) to aerosolize the powder in the receptacle by flowing gas through the chamber.

Independent claim 37 is directed to a powder dispersion device comprising a housing that is adapted to receive a receptacle (10) having an enclosed chamber (18) containing an amount of a powder; an aerosolization system (an example of which is discussed on page 13 lines 7-26) in the housing to extract the powder from the receptacle and to entrain the powder in a gas stream to form an aerosol by flowing gas through the chamber; and a mechanism (22) to provide at least one pulse of energy to the receptacle prior to aerosolization to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber.

Independent claim 46 is directed to a kit for aerosolizing a powder as described on page 5 lines 4-18). The kit comprises at least one receptacle (10) having an enclosed chamber (18) containing an amount of a powder, an aerosolization device (an example of which is discussed on page 13 lines 7-26) having an opening for receiving the receptacle, the aerosolization device also having an aerosolization mechanism to aerosolize the powder in the receptacle by flowing gas through the chamber. The kit further comprises instructions describing a method for providing at least one pulse of energy to the receptacle prior to aerosolizing the powder.

Independent claim 54 is directed to a powder conditioning device (22) comprising a container (as discussed beginning on page 16 line 26) that is adapted to hold a receptacle (10) having an enclosed chamber (18) containing an amount of a powder; and a mechanism (160) coupled to the container that is operable to provide at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber. The container

6506206395

PATENT

Attorney Docket No. 015225-005210US (0051.00)

Serial No. 09/731,316

comprises a base (162) and a cover (164) that is pivotally coupled to the base, the base and the cover defining an enclosure which is adapted to receive the receptacle, and further comprising a coupling arrangement (172) adapted to couple the receptacle to the base. The mechanism comprises a hook (182) coupled to the cover that is adapted to engage and then release the receptacle when the cover is pivoted to permit the receptacle to strike the base.

Independent claim 55 is directed to a powder conditioning device comprising a container (as discussed beginning on page 16 line 26) that is adapted to hold a receptacle (10) having an enclosed chamber (18) containing an amount of a powder and a mechanism (186) coupled to the container that is operable to provide at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber. The container comprises a base (188) and a cover (190) that is pivotally coupled to the base, the base and the cover defining an enclosure which is adapted to receive the receptacle, and further comprising a coupling arrangement (196) adapted to couple the receptacle to the base. The coupling arrangement is pivotally coupled to the base, and wherein the mechanism comprises a latch (204) that is operably coupled to the base, an arm (202) that is coupled to the cover, and a cantilever beam (200) that is attached to the coupling arrangement, wherein the arm is configured to engage and pivot the coupling arrangement as the cover is opened, and wherein the latch is configured to engage and then release the cantilever beam when the coupling arrangement is pivoted to permit the cantilever beam to strike the receptacle.

Independent claim 57 is directed to a powder conditioning device comprising a container (as discussed beginning on page 16 line 26) that is adapted to hold a receptacle (10) having an enclosed chamber (18) containing an amount of a powder and a mechanism (206) coupled to the container that is operable to provide at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber. The container comprises a base (208) and a cover (210) that is pivotally coupled to the base, the base and the cover defining an enclosure which is adapted to receive the receptacle, and further comprising a coupling arrangement (212) adapted to couple the receptacle to

Attorney Docket No. 015225-005210US (0051.00)

Serial No. 09/731,316

the base. The mechanism comprises a spring (222) that is coupled to the cover and a latch (220) that is operably coupled to the base, wherein the latch is operable to release the spring to permit the spring to strike the receptacle.

Independent claim 59 is directed to a powder conditioning device comprising a container (as discussed beginning on page 16 line 26) that is adapted to hold a receptacle (10) having an enclosed chamber (18) containing an amount of a powder and a mechanism (250) coupled to the container that is operable to provide at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber. The container is adapted to hold a plurality of stacked receptacles, and wherein the mechanism comprises a biased striking member (see Figure 29 and page 19 lines 19-34) and a trigger (266) that is movable between a home position and a striking position, wherein movement of the trigger to the striking position releases the striking member to permit the striking member to strike one of the receptacles.

Independent claim 61 is directed to a method for aerosolizing a powder comprising placing a receptacle (10) having a chamber (18) containing an amount of a powder into an aerosolization device having an aerosolization system for extracting the powder from the receptacle by flowing gas through the chamber to form an aerosol, and a mechanism to provide at least one pulse of energy to the receptacle and providing a pulse of energy to the receptacle using the mechanism and actuating the aerosolization system to extract the powder from the receptacle.

(6) Grounds of Rejection to be Reviewed on Appeal

Appellant requests review of the Examiner's following grounds of rejection:
Claims 1, 3-7, 11, 15, 16, 18, 21, 25-29, 38, 39, 45-49, 61, and 62 have been rejected under 35 USC 103(a) as being unpatentable over U.S. Patent 5,740,794 to Smith et al (hereinafter Smith et al) in view of PCT Publication WO 99/44663 to McGinn et al (hereinafter McGinn et al).

Claims 1, 8-11, 13-15, 23, 24, 26, 27, 37, 43-45, and 61 have been rejected under 35 USC 103(a) as being unpatentable over Smith et al in view of US Patent 5,694,920 to Abrams et al (hereinafter Abrams et al).

Attorney Docket No. 015225-005210US

Serial No. 09/731,316

Claim 2 has been rejected under 35 USC 103(a) as being unpatentable over Smith et al and McGinn et al further in view of U.S. Patent 6,167,880 to Gorda et al (hereinafter Gorda et al).

Claim 12 has been rejected under 35 USC 103(a) as being unpatentable over Smith et al and McGinn et al further in view of Abrams et al.

(7) Argument

Appellant believes each of claims 1-18, 21, 23-29, 35-39, 43-49, 61 and 62 are improperly rejected and are therefore allowable for the following reasons.

The rejection of independent claim 1 under 35 U.S.C. 103(a) is improper

The Examiner's rejection of independent claim 1 under 35 USC 103(a) as being unpatentable over Smith et al in view of PCT McGinn et al is improper.

Smith et al does not render claim 1 unpatentable. Claim 1 is to a method for conditioning a packaged powder, the method comprising, inter alia, the step of providing at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber and the step of flowing a gas through the chamber to aerosolize the powder. Smith et al discloses the step of flowing a gas through the chamber to aerosolize the powder but does not disclose or suggest the step of providing at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber. Thus, Smith et al alone does not render claim 1 unpatentable.

McGinn et al also does not render claim 1 unpatentable. As discussed above, claim 1 is to a method for conditioning a packaged powder, the method comprising, inter alia, the step of providing at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber and the step of flowing a gas through the chamber to aerosolize the powder. McGinn et al discloses the application of a pulse of energy. However, in McGinn, the application of a pulse of energy is for the purpose of aerosolization. McGinn et al does not disclose providing a pulse of energy to increase aerosolization efficiency *and* flowing a gas through the

Attorney Docket No. 015225-005210US (0051.00)

Serial No. 09/731,316

chamber to aerosolize the powder. Thus, McGinn et al alone also fails to render claim 1 unpatentable.

Furthermore, claim 1 is also not rendered unpatentable by the combination of Smith et al and McGinn et al. Smith et al and McGinn et al disclose two different types of aerosolization mechanisms. Neither teaches a system such as that claimed where a step comprises the application of a pulse of energy to increase the efficiency at which the powder may be extracted from the chamber and another step comprises flowing a gas through the chamber to aerosolize the powder. In the case of Smith et al, there is no pulse of energy and in the case of McGinn et al the burst of energy is for the purpose of forming an aerosolized cloud (page 24 lines 16-20). The Examiner appears to be of the position that one of ordinary skill in the art would have found it obvious to use two different types of aerosolization mechanisms in the same device. However, this modification is not suggested by the prior art and would therefore not have been obvious. Moreover, the person of ordinary skill would not have found it obvious to make the proposed modification when considering the teaching of the references as a whole. As can be seen in Figures 12A and 12B of Smith et al, the aerosolization mechanism of Smith et al is the flowing of air and the drawing of powder through the feedtube (element 106). If one were to provide a pulse of energy to aerosolize a cloud of powder in accordance with the teachings of McGinn et al it is unclear where cloud would be generated and more importantly why the cloud would be necessary. Therefore, since there is no suggestion to combine two disparate aerosolization mechanisms and because it is unclear how or why they would be combined anyway, one of ordinary skill in the art at the tine the invention was made would not have found it obvious in view of Smith et al and McGinn et al to arrive at the invention of present claim 1.

Clearly the only way to construct the Examiner's proposed modification is through impermissible hindsight reasoning, using the Appellant's specification as the blueprint for the modification. Such hindsight reasoning is not permissible where there is no suggestion for making the modification, as in the present situation. In addition, it is even more impermissible when the resulting modification would result in a surplusage of aerosolization mechanisms.

PATENT Attorney Docket No. 015225-005210US

Serial No. 09/731,316

The Examiner's rejection of claim 1 under 35 USC 103(a) as being unpatentable over Smith et al in view of Abrams et al is also improper.

Smith et al and Abrams et al do not render claim 1 unpatentable. Claim 1 is to a method for conditioning a packaged powder, the method comprising, inter alia, the step of providing at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber and the step of flowing a gas through the chamber to aerosolize the powder. Smith et al does not teach the method of claim 1, as discussed above.

Additionally, Abrams does not teach the method of claim 1. Abrams discloses vibrating a powder for deaggregation of the powder. However, Abrams does not disclose the steps of providing a pulse of energy *and* flowing a gas through the chamber to aerosolize the powder. Instead, Abrams aerosolizes the powder using electrostatic charge. If one of ordinary skill in the art at the time the invention were to modify the Smith et al device in accordance with the teachings of Abrams et al as a whole, then a vibration/electrostatic aerosolization mechanism would be used instead of the air flow aerosolization recited in claim 1. Thus, one of ordinary skill in the art would not have been motivated, based on the teachings of Smith et al as a whole and Abrams et al as a whole, to arrive at the invention recited in present claim 1. The Examiner may not pick and choose aspects of the various references and combine them in a manner that reads on Appellant's claim, absent a suggestion to do so. Instead, the teachings of the references as a whole must be considered. When the teachings of Abrams et al as a whole are considered, the reference is not combinable with Smith et al in a way that renders claim 1 unpatentable.

In the Final Office action dated October 6, 2005, the states in Paragraph 1 that "[t]he mechanical pulse provided by McGinn et al provided to the receptacle of Smith et al is an obvious alternative to the pulse of air provided to the powder itself to deagglomerate/fluidize for breaking up the agglomerate. The same applies for Abrams et al." Assuming *in arguendo* that the proposed "alternative" is viable and obvious, the resulting modification would not include both steps recited in claim 1.

The rejection of independent claim 15 is also improper

Smith et al and McGinn et al do not render claim 15 unpatentable. Claim 15 is to a powder conditioning system comprising, inter alia, a receptacle, a mechanism to provide at least one pulse of energy to the receptacle, and an aerosolization mechanism to aerosolize powder in the receptacle by flowing gas through the chamber. As discussed above, Smith et al and McGinn et al do not teach both a mechanism to provide a pulse of energy *and* an aerosolization mechanism of the type claimed. Therefore, Smith et al and McGinn et al do not render claim 15.

In addition, Smith et al and Abrams et al do not render claim 15 unpatentable. Smith et al and Abrams et al do not disclose a mechanism to provide a pulse of energy and an aerosolization mechanism that aerosolizes by flowing gas through the chamber. Therefore, Smith et al and Abrams et al do not render claim 15.

The rejection of independent claim 37 is also improper

Smith et al and Abrams et al do not render claim 37 unpatentable. Claim 37 is to a powder dispersion device comprising, inter alia, an aerosolization system in the housing to extract the powder from the receptacle and to entrain the powder in a gas stream to form an aerosol by flowing gas through a chamber and a mechanism to provide at least one pulse of energy to the receptacle prior to aerosolization to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber. As discussed above, neither Smith et al nor Abrams et al disclose an aerosolization system in the housing to extract the powder from the receptacle and to entrain the powder in a gas stream to form an aerosol by flowing gas through a chamber and a mechanism to provide at least one pulse of energy to the receptacle prior to aerosolization to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber. Therefore, Smith et al and Abrams et al do not render claim 37 and its depending claims unpatentable.

The rejection of independent claim 46 is also improper

Smith et al and McGinn et al do not render claim 46 unpatentable. Claim 46 is to a kit for aerosolizing a powder, the kit comprising, inter alia, at least one receptacle having an enclosed chamber containing an amount of a powder, an aerosolization device having an opening for receiving the receptacle, the aerosolization device also having an aerosolization mechanism to aerosolize the powder in the receptacle by flowing gas through the chamber, and instructions describing a method for providing at least one pulse of energy to the receptacle prior to aerosolizing the powder. As discussed above, Smith et al and McGinn et al do not teach both a mechanism to provide a pulse of energy **and** an aerosolization mechanism of the type claimed. Since the references do not teach a mechanism for providing a pulse of energy, the references do not include the instructions as recited. Therefore, Smith et al and McGinn et al do not render claim 46.

The rejection of independent claim 61 is also improper

Smith et al and McGinn et al do not render claim 61 unpatentable. Claim 61 is to a method for aerosolizing a powder comprising, inter alia, placing a receptacle into an aerosolization device having an aerosolization system for extracting the powder from the receptacle by flowing gas through a chamber and a mechanism to provide at least one pulse of energy to the receptacle. Smith et al and McGinn et al do not teach a system for extracting a powder by flowing gas through a chamber and a mechanism to provide a pulse of energy to a receptacle, as discussed above. Accordingly, Smith et al and McGinn et al do not render claim 61. Smith et al and Abrams et al similarly fail to render claim 61 unpatentable.

The dependent claims are allowable for at least the same reasons as their base claims

Claims 2-14 depend from improperly rejected claim 1. Claims 16-36 depend from improperly rejected claim 15. Claims 38-45 depend from improperly rejected claim 37. Claims 47-50 depend from improperly rejected claim 46. Claims 62 and 63 depends from improperly rejected claim 61. Since claims 2-14, 16-36, 38-45, 47-50, 62

Attorney Docket No. 015225-005210US (0051.00)

Serial No. 09/731,316

and 63 include the limitations of the claims from which they depend, they are not rendered unpatentable for at least the same reason as their base claim.

The Examiner also rejected claim 2 under 35 USC 103(a) as being unpatentable over Smith et al and McGinn et al further in view of Gorda et al. The proposed modifications do not make up for the deficiencies of Smith et al and McGinn et al discussed above in connection with independent claim 1. Accordingly, claim 2 is not rendered unpatentable by Smith et al, McGinn et al and Gorda et al.

The Examiner also rejected claim 12 under 35 USC 103(a) as being unpatentable over Smith et al and McGinn et al further in view of Abrams et al. The proposed modifications do not make up for the deficiencies of Smith et al, McGinn et al and Abrams et al discussed above. Accordingly, claim 12 is not rendered unpatentable by Smith et al, McGinn et al and Abrams et al.

Conclusion

Thus, it is believed that all rejections made by the Examiner have been addressed and overcome by the above arguments. Therefore, all pending claims are allowable. A reversal is respectfully requested.

Should there be any questions, Appellant's representative may be reached at the number listed below.

Respectfully submitted.

Dated: <u>28 550 200</u> 7

Ğuy ∜. Tucker Reg. No. 45,302

Please send all correspondence to: Guy Tucker Nektar Therapeutics (formerly Inhale Therapeutic Systems, Inc.) 201 Industrial Road San Carlos, CA 94070

Phone: (650) 620-5501 Fax: (650) 631-3125

PATEN7
Attorney Docket No. 015225-005210US

Serial No. 09/731,316

(8) Claims Appendix

1. A method for conditioning a packaged powder, the method comprising:

providing a receptacle having an enclosed chamber containing an amount of a powder;

providing at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber; and flowing a gas through the chamber to aerosolize the powder.

- 2. A method as in claim 1, further comprising providing the pulse of energy while the powder is sealed within the chamber.
- 3. A method as in claim 1, wherein the pulse providing step further comprises quickly striking the receptacle.
- 4. A method as in claim 3, further comprising striking the receptacle with an amount of energy of at least about 0.01 lbf-in.
- 5. A method as in claim 3, further comprising releasing a springloaded lever to quickly strike the receptacle.
- 6. A method as in claim 1, wherein the pulse providing step further comprises moving the receptacle past an arm that temporarily engages a portion of the receptacle.
- 7. A method as in claim 1, wherein the pulse providing step further comprises bending and quickly releasing receptacle to permit receptacle to strike a surface.

6506206395

PATENT

Attorney Docket No. 015225-005210US (0051.00)

Serial No. 09/731,316

- 8. A method as in claim 1, wherein the pulse providing step further comprises providing a pulse of vibratory energy to the receptacle.
- 9. A method as in claim 8, further comprising contacting the receptacle with a vibrating piezoelectric transducer to provide the vibratory energy.
- 10. A method as in claim 9, further comprising vibrating the transducer at a frequency of at least about 10 kHz.
- 11. A method as in claim 1, wherein the powder is composed of fine particles having a mean size in the range from about 0.5 μ m to about 5 μ m.
- 12. A method as in claim 1, further comprising providing at least one pre-conditioning step prior to providing said at least one pulse of energy, wherein said pre-conditioning step comprises vibrating the receptacle for a predetermined period of time.
- 13. A method as in claim 1, wherein the receptacle is vibrated at a frequency within the range of about 0.01 Hz to about 500 Hz.
- 14. A method as in claim 1, wherein the receptacle is vibrated for about 0.01 minute to about 10 minutes.
- 15. A powder conditioning system comprising:
 a receptacle having an enclosed chamber containing an amount of a powder;

a mechanism to provide at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber; and

an aerosolization mechanism to aerosolize the powder in the receptacle by flowing gas through the chamber.

Attorney Docket No. 015225-005210US

Serial No. 09/731,316

- 16. A system as in claim 15, wherein the mechanism to provide at least one pulse of energy to the receptacle comprises a striking device to quickly strike the receptacle.
- 17. A system as in claim 16, wherein the striking device is configured to strike the receptacle with at least about 0.01 lbf-in in energy.
- 18. A system as in claim 16, wherein the striking device comprises a spring-loaded lever arm, and a release apparatus to release the lever arm.
- 19. A system as in claim 18, further comprising a pivotal latch having a lock that pivots as the receptacle is moved against the latch, and a trigger having a ramp, wherein the lock of the latch is slidable upon the ramp when the latch pivots to cause the lever arm to pivot and compress a first spring and cause the lock to engage the trigger to lock the lever arm in an energy storage position.
- 20. A system as in claim 19, further comprising a second spring that is in contact with the trigger, wherein further movement of the receptacle causes the receptacle to engage and move the trigger away from the lock to release the lever arm which then strikes the receptacle.
- 21. A system as in claim 15, wherein the mechanism to provide at least one pulse of energy to the receptacle comprises a bending device that is configured to bend and then quickly release the receptacle to permit the receptacle to strike a surface.
- 22. A system as in claim 15, wherein the mechanism to provide at least one pulse of energy to the receptacle comprises an arm that is mounted to a frame, and a movable platform to move the receptacle past the arm while temporarily engaging the arm.

Attorney Docket No. 015225-005210US (0051.00)

Serial No. 09/731,316

- 23. A system as in claim 15, wherein the mechanism to provide at least one pulse of energy to the receptacle comprises a vibratable element that is configured to at least temporarily contact the receptacle.
- 24. A system as in claim 23, wherein the vibratable element comprises a piezoelectric transducer.
- 25. A system as in claim 15, wherein the receptacle further comprises a metallic body having a tab extending from the chamber.
- 26. A system as in claim 15, wherein the powder is composed of fine particles having a mean size in the range from about 0.5 μ m to about 5 μ m.
- 27. A system as in claim 15, further comprising a container having an enclosure, wherein the receptacle is held within the enclosure, and wherein the mechanism to provide at least one pulse of energy to the receptacle is coupled to the container.
- 28. A system as in claim 27, wherein the container comprises a base and a cover that is pivotally coupled to the base, wherein the base and the cover define the enclosure.
- 29. A system as in claim 28, further comprising a coupling arrangement that couples the receptacle to the base.
- 30. A system as in claim 28, wherein the mechanism to provide at least one pulse of energy to the receptacle comprises a hook coupled to the cover that engages and then releases the receptacle when the cover is pivoted to permit the receptacle to strike the base.

6506206395

PATENT Attorney Docket No. 015225-005210US (0051.00) Serial No. 09/731,316

- 31. A system as in claim 29, wherein the coupling arrangement is pivotally coupled to the base, and wherein the mechanism to provide at least one pulse of energy to the receptacle comprises a latch that is operably coupled to the base, an arm that is coupled to the cover, and a cantilever beam that is attached to the coupling arrangement, wherein the arm is configured to engage and pivot the coupling arrangement as the cover is opened, and wherein the latch is configured to engage and then release the cantilever beam when the coupling arrangement is pivoted to permit the cantilever beam to strike the receptacle.
- 32. A system as in claim 31, wherein the latch is slidably coupled to the base such that the latch may be moved over the cantilever beam after the receptacle has been positioned within the enclosure.
- 33. A system as in claim 28, wherein the mechanism to provide at least one pulse of energy to the receptacle comprises a spring that is coupled to the cover and a latch that is operably coupled to the base, wherein the latch is operable to release the spring to permit the spring to strike the receptacle.
- 34. A system as in claim 33, wherein the latch is slidably coupled to the base such that the latch may be moved to release the spring after the cover has been closed.
- 35. A system as in claim 15, further comprising a housing and a plurality of receptacles that are stacked within the housing, and wherein the mechanism to provide at least one pulse of energy to the receptacle comprises a biased striking member and a trigger that is movable between a home position and a striking position, wherein movement of the trigger to the striking position releases the striking member to permit the striking member to strike one of the receptacles.

6506206395

Attorney Docket No. 015225-005210US

Serial No. 09/731,316

- A system as in claim 35, further comprising an advancement 36. apparatus that is configured to advance the receptacles toward the striking member upon movement of the trigger to the striking position, and further comprising a push plate coupled to the trigger such that movement of the trigger back to the home position pushes a treated receptacle from the housing.
 - 37. A powder dispersion device, comprising:

a housing that is adapted to receive a receptacle having an enclosed chamber containing an amount of a powder;

an aerosolization system in the housing to extract the powder from the receptacle and to entrain the powder in a gas stream to form an aerosol by flowing gas through the chamber;

a mechanism to provide at least one pulse of energy to the receptacle prior to aerosolization to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber.

- 38. A device as in claim 37, wherein the mechanism comprises a striking device disposed in the housing to quickly strike the receptacle.
- A device as in claim 37, wherein the striking device comprises a 39. spring-loaded lever arm, and a release apparatus to release the lever arm.
- 40. A device as in claim 37, further comprising a pivotal latch having a lock that pivots as the receptacle is moved against the latch, and a trigger having a ramp, wherein the lock of the latch is slidable upon the ramp when the latch pivots to cause the lever arm to pivot and compress a first spring and cause the lock to engage the trigger to lock the lever arm in an energy storage position.

- 41. A device as in claim 40, further comprising a second spring that is in contact with the trigger, wherein further movement of the receptacle causes the receptacle to engage and move the trigger away from the lock to release the lever arm which then strikes the receptacle.
- 42. A device as in claim 37, wherein the mechanism comprises an arm that is operably mounted to the housing, and a movable platform to move the receptacle past the arm while temporarily engaging the arm.
- 43. A device as in claim 37, wherein the mechanism comprises a vibratable element in the housing that is configured to at least temporarily contact the receptacle.
- 44. A device as in claim 43, wherein the vibratable element comprises a piezoelectric transducer.
- 45. A device as in claim 37, wherein the aerosolization system comprises a mouthpiece that is adapted to receive a patient's mouth to permit the patient to create the gas stream.
- 46. A kit for aerosolizing a powder, comprising: at least one receptacle having an enclosed chamber containing an amount of a powder;

an aerosolization device having an opening for receiving the receptacle, the aerosolization device also having an aerosolization mechanism to aerosolize the powder in the receptacle by flowing gas through the chamber; and instructions describing a method for providing at least one pulse of energy to the receptacle prior to aerosolizing the powder.

47. A kit as in claim 46, wherein the instructions describe manually striking the receptacle with a finger or a hard surface.

- 48. A kit as in claim 46, further comprising a powder conditioning device, and wherein the instructions describe placing the receptacle into the powder conditioning device prior to placing the receptacle into the aerosolization device.
- 49. A kit as in claim 48, wherein the powder conditioning device comprises a frame and a spring-loaded lever arm pivotally coupled to the frame, wherein the lever arm is releasable to strike the receptacle.
- 50. A kit as in claim 49, wherein the instructions describe placing the receptacle into the aerosolization device and operating a button on the aerosolization device to supply an amount of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber when operating the device.
- 52. A device as in claim 59, wherein the container comprises a base and a cover that is pivotally coupled to the base, wherein the base and the cover define an enclosure which is adapted to receive the receptacle.
- 53. A device as in claim 52, further comprising a coupling arrangement is adapted to couple the receptacle to the base.
- 54. A powder conditioning device comprising:

 a container that is adapted to hold a receptacle having an enclosed chamber containing an amount of a powder; and

a mechanism coupled to the container that is operable to provide at least one pulse of energy to the receptable to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber,

wherein the container comprises a base and a cover that is pivotally coupled to the base, the base and the cover defining an enclosure which is adapted to receive the receptacle, and further comprising a coupling arrangement adapted to couple the receptacle to the base, and

Attorney Docket No. 015225-005210US (0051.00)

Serial No. 09/731,316

wherein the mechanism comprises a hook coupled to the cover that is adapted to engage and then release the receptacle when the cover is pivoted to permit the receptacle to strike the base.

55. A powder conditioning device comprising:

a container that is adapted to hold a receptacle having an enclosed chamber containing an amount of a powder; and

a mechanism coupled to the container that is operable to provide at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber,

wherein the container comprises a base and a cover that is pivotally coupled to the base, the base and the cover defining an enclosure which is adapted to receive the receptacle, and further comprising a coupling arrangement adapted to couple the receptacle to the base, wherein the coupling arrangement is pivotally coupled to the base, and wherein the mechanism comprises a latch that is operably coupled to the base, an arm that is coupled to the cover, and a cantilever beam that is attached to the coupling arrangement, wherein the arm is configured to engage and pivot the coupling arrangement as the cover is opened, and wherein the latch is configured to engage and then release the cantilever beam when the coupling arrangement is pivoted to permit the cantilever beam to strike the receptacle.

- 56. A device as in claim 55, wherein the latch is slidably coupled to the base such that the latch may be moved over the cantilever beam after the receptacle has been positioned within the enclosure.
 - 57. A powder conditioning device comprising:

a container that is adapted to hold a receptacle having an enclosed chamber containing an amount of a powder; and

a mechanism coupled to the container that is operable to provide at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber,

wherein the container comprises a base and a cover that is pivotally coupled to the base, the base and the cover defining an enclosure which is adapted to receive the receptacle, and further comprising a coupling arrangement adapted to couple the receptacle to the base, and

wherein the mechanism comprises a spring that is coupled to the cover and a latch that is operably coupled to the base, wherein the latch is operable to release the spring to permit the spring to strike the receptacle.

- 58. A device as in claim 57, wherein the latch is slidably coupled to the base such that the latch may be moved to release the spring after the cover has been closed.
- 59. A powder conditioning device comprising:
 a container that is adapted to hold a receptacle having an enclosed chamber containing an amount of a powder; and

a mechanism coupled to the container that is operable to provide at least one pulse of energy to the receptacle to increase the efficiency at which the powder may be extracted from the chamber when flowing a gas through the chamber,

wherein the container is adapted to hold a plurality of stacked receptacles, and wherein the mechanism comprises a biased striking member and a trigger that is movable between a home position and a striking position, wherein movement of the trigger to the striking position releases the striking member to permit the striking member to strike one of the receptacles.

60. A device as in claim 59, further comprising an advancement apparatus that is configured to advance the receptacles toward the striking member upon movement of the trigger to the striking position, and further comprising a push plate coupled to the trigger such that movement of the trigger back to the home position pushes a treated receptacle from the container.

61. A method for aerosolizing a powder, the method comprising:

placing a receptacle having a chamber containing an amount of a
powder into an aerosolization device having an aerosolization system for extracting the
powder from the receptacle by flowing gas through the chamber to form an aerosol, and
a mechanism to provide at least one pulse of energy to the receptacle; and

providing a pulse of energy to the receptacle using the mechanism
and actuating the aerosolization system to extract the powder from the receptacle.

NEKTAR

- 62. A method as in claim 61, wherein the pulse of energy is provided within about 100 ins before actuation of the aerosolization system to about 25 ms after actuation of the aerosolization system.
- 63. A method as in claim 61, wherein the emitted dose is increased by about 10% when the pulse of energy is provided at about the same time as actuation of the aerosolization system.

(9) Evidence Appendix None

6506206395

Attorney Docket No. 015225-005210US

Serial No. 09/731,316

(10) Related Proceedings Appendix None